

Attorney/Docket No. 36689.140
Customer No. 000027683

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Lewin et al.

Appl. No. 09/847,601

Filed: 05/01/2001

For: Adeno-Associated Virus-Delivered Ribozyme
Compositions and Methods for the Treatment of
Retinal Diseases

§ Confirmation Number: 7183
§
§ Group Art Unit: 1632
§
§ Examiner: Chong, Kimberly
§
§
§

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In compliance with the duty of disclosure under 37 CFR §1.56, and in accordance with the practice under 37 CFR §1.97 and §1.98, the Examiner's attention is directed to the documents listed on the enclosed modified Form PTO-1449. No inference should be made that the cited references are in fact material, are in fact prior art, or that no better art exists. The cited patents are listed in numerical order and are not in any order based on their pertinence.

Pursuant to 37 CFR 1.98 (a)(2)(i), copies of the U.S. patent documents listed on the enclosed modified Form PTO-1449 are not attached.

This Information Disclosure Statement is being filed more than three months after the United States filing date and after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Action under §1.113 or Notice of Allowance under §1.311 (37 CFR §1.97(c)).

Accompanying this transmittal is the \$180.00 fee set forth in 37 CFR §1.17(p) for submission of an Information Disclosure Statement under §1.97(c).

The Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to Deposit Account 08-1394.

12/30/2005 HLE333 00000024 081394 09847601
01 FC:1806 180.00 DA

H-586498

It is respectfully requested that the above information be considered by the Examiner and that a copy of the enclosed Form PTO-1449 be returned indicating that such information has been considered.

Respectfully submitted,



Mark D. Moore, Ph.D.

Registration No. 42,903

Date: 22 DEC 2005
HAYNES AND BOONE, LLP
901 Main Street, Suite 3100
Dallas, Texas 75202-3789
Telephone: 713-547-2040
Facsimile: 214-200-0853
File: 36689.140

Certificate of Mailing

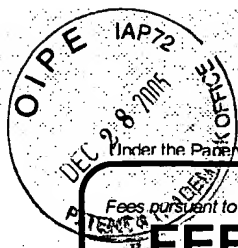
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 12/22/05.

Kim Hennessey

Printed Name

Kim Hennessey

Signature



PTO/SB/17 (12-04)

Approved for use through 07/31/2006: OMB 0651-0032

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Effective on 12/08/2004.

Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

**FEE TRANSMITTAL
For FY 2005**☐ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT** (\$ 180.00)**Complete If Known**

Application Number 09/847,601

Filing Date 05/01/2001

First Named Inventor Lewin

Examiner Name Chong, Kimberly

Art Unit 1632

Attorney Docket No. 36689.140

METHOD OF PAYMENT (check all that apply)☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify) _____☒ Deposit Account Deposit Account Number 08-1394 Deposit Account Name Haynes and Boone, LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below☐ Charge fee(s) indicated below, except for the filing fee☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17☐ Credit any overpayments**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.****FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

Total Claims **Extra Claims** **Fee (\$)** **Fee Paid (\$)**

- 20 or HP = _____ x _____ = _____

HP = highest number of total claims paid for, if greater than 20

Indep. Claims **Extra Claims** **Fee (\$)** **Fee Paid (\$)**

- 3 or HP = _____ x _____ = _____

HP = highest number of independent claims paid for, if greater than 3

Multiple Dependent Claims**Fee (\$)** **Fee Paid (\$)****3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets **Extra Sheets** **Number of each additional 50 or fraction thereof** **Fee (\$)** **Fee Paid (\$)**

- 100 = _____ / 50 = _____ (round up to a whole number) x _____ = _____

4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other: Information Disclosure Statement Fee

Fees Paid (\$)
\$180.00**SUBMITTED BY**

Signature		Registration No. (Attorney/Agent) 42,903	Telephone 713-547-2040
Name (Print/Type)	Mark D. Moore, Ph.D.		Date 12/22/2005

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 422 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

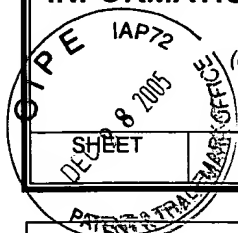
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Application Number 09/847,601
Filing Date May 1, 2001
Applicant(s) Lewin *et al.*
Art Unit 1632
Examiner Name Unknown
Attorney Docket Number 36689.140



U. S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		4,683,195	07-28-1987	Mullis <i>et al.</i>
		4,683,202	07-28-1987	Mullis
		4,800,159	01-24-1989	Mullis <i>et al.</i>
		4,883,750	11-28-1989	Whiteley <i>et al.</i>
		5,297,721	03-29-1994	Schneider <i>et al.</i>
		5,334,711	08-02-1994	Sproat <i>et al.</i>
		5,354,855	10-11-1994	Cech <i>et al.</i>
		5,455,166	10-03-1995	Walker
		5,631,359	05-20-1997	Chowrira <i>et al.</i>
		5,648,211	07-15-1997	Fraiser <i>et al.</i>
		5,712,124	01-27-1998	Walker
		5,744,311	04-28-1998	Fraiser <i>et al.</i>
		6,225,291	05-01-2001	Lewin <i>et al.</i>
		6,943,153	09-13-2005	Manning <i>et al.</i>
		2001/0034054 A1	10-25-2001	Dwarki <i>et al.</i>
		2001/0051611 A1	12-13-2001	Srivastava <i>et al.</i>
		2002/0132336 A1	09-19-2002	Dwarki <i>et al.</i>
		2002/0194630 A1	12-19-2002	Manning <i>et al.</i>
		2003/0166284 A1	09-04-2003	Srivastava <i>et al.</i>

Examiner's Initial	Cite No.	Foreign Patent Document (Country Code - Number - Kind)	Publication Date MM-DD-YYYY	Patentee or Applicant of Cited Document	Translation Y/N
		EP 0320308	11-03-1993	Abbott Laboratories	
		EP 0329822	06-08-1994	Cangene Corporation	
		EP 0360257	03-28-1990	The Board of Regents for Northern Illinois University Biotechnology Research and Development Corp. Inc.	
		GB 2202328	09-21-1988	Orion-Yhtymä Oy	
		WO 87/06270	10-22-1987	The Salk Institute for Biological Studies	
		WO 88/10315	12-29-1988	Siska Diagnostics, Inc.	
		WO 89/06700	07-27-1989	Genetech, Inc.	
		WO 89/09284	10-05-1989	University of Iowa Research Foundation	
		WO 90/07641	07-12-1990	Sundstrand Corporation	
		WO 91/03162	03-21-1991	City of Hope	
		WO 92/07065	04-30-1992	Maxplanck-Gesellschaft Zur Förderung der Wissenschaften E.V.	
		WO 93/15187	08-05-1993	Massachusetts Institute of Technology	
		WO 93/23569	11-25-1993	Ribozyme Pharmaceuticals, Inc.	
		WO 94/02595	02-03-1994	Ribozyme Pharmaceuticals, Inc.	
		WO 94/13688	06-23-1994	Gene Shears Pty. Limited	
		WO 00/54813 A2	09-21-2000	Manning <i>et al.</i>	
		WO 02/24234 A2	03-28-2002	McGee <i>et al.</i>	
		WO 02/088320 A2	11-07-2002	University of Florida	

Examiner Signature	Date Considered
--------------------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

In place of PTO-1449 Form		U. S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	09/847,601
				Filing Date	May 1, 2001
				Applicant(s)	Lewin <i>et al.</i>
				Art Unit	1632
				Examiner Name	Unknown
SHEET	2	OF	2	Attorney Docket Number	36689.140

NON-PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article, title of the item, date, page(s), volume-issue number(s), publisher, city/country where published
		AFZAL <i>et al.</i> , "Reduction on Preretinal Neovascularization by Ribozymes that Cleave the A _{2B} Adenosine Receptor mRNA," <i>Circulation Research</i> , 93 , September 23, 2003.
		BERGSLAND <i>et al.</i> , "Update on Clinical Trials Targeting Vascular Endothelial Growth Factor in Cancer," <i>Am. J. Health Syst. Pharm.</i> , 61 (5):S12-S20, November 2004.
		BLALOCK <i>et al.</i> , "Hammerhead ribozyme targeting connective tissue growth factor mRNA blocks transforming growth factor-beta mediated cell proliferation," <i>Experimental Eye Research</i> , 78 :1127-1136, 2004.
		CORDIERO <i>et al.</i> , "Molecular Therapy in Ocular Wound Healing," <i>BJO Online</i> , 83 :1219-1224, 1999.
		FARRAR <i>et al.</i> , "On the Genetics of Retinitis Pigmentosa and on Mutation-Independent Approaches to Therapeutic Intervention," <i>EMBO J.</i> , 21 (5):857-864, 2002.
		FRITZ <i>et al.</i> , "Design and Validation of Therapeutic Hammerhead Ribozymes for Autosomal Dominant Diseases," <i>Methods Mol. Bio.</i> , 252 :221-36, 2004.
		FRITZ <i>et al.</i> , "Designing and Characterizing Hammerhead Ribozymes for Use in AAV Vector-Mediated Retinal Gene Therapies," <i>Methods Enzymol.</i> , 346 :358-77, 2002.
*		FRITZ <i>et al.</i> , "Development of Hammerhead Ribozymes to Modulate Endogenous Gene Expression For Functional Studies," <i>Methods</i> , 28 (2):276-85, October 2002.
*		GORBATYUK <i>et al.</i> , "Knockdown of Wild-Type Mouse Rhodopsin Using an AAV Vectored Ribozyme as Part of an RNA Replacement Approach," <i>Mol. Vis.</i> , 11 :648:56, August 29, 2005.
		HAUSWIRTH <i>et al.</i> , "Range of Retinal Disease Potentially Treatable by AAV-vectored Gene Therapy," <i>Novartis Found. Symp.</i> , 255 :179-194, 2004.
		HAUSWIRTH <i>et al.</i> , "Ribozyme Gene Therapy for Autosomal Dominant Retinal Disease," <i>Clin. Chem. Lab. Med.</i> 2000 , 38 (2):147-153, 2000.
		HAUSWIRTH <i>et al.</i> , "Ribozyme Uses in Retinal Gene Therapy," <i>Prog. Retin. Eye Res.</i> , 19 (6):689-710, November 2000.
		LEWIN <i>et al.</i> , "Gene Therapy for Autosomal Dominant Disorders of Keratin," <i>J. Investig. Dermatol. Symp. Proc.</i> , 10 (1):47-61, 2005.
		LEWIN <i>et al.</i> , "Ribozyme Gene Therapy: Applications for Molecular Medicine," <i>Trends Mol. Med.</i> , 7 (5):221-8, May 2001.
		LIU <i>et al.</i> , "Ribozyme Knockdown for the Gamma-Subunit of Rod cGMP Phosphodiesterase Alters the ERG and Retinal Morphology in Wild-Type Mice," <i>Invest. Ophthalmol. Vis. Sci.</i> , 46 (10):3836-44, October 2005.
		QI <i>et al.</i> , "Optic Neuropathy Induced by Reductions in Mitochondrial Superoxide Dismutase," <i>Invest. Ophthalmol. Vis. Sci.</i> , 44 (3): 1088-96, March 2003.
		QI <i>et al.</i> , "SOD2 Gene Transfer Protects Against Optic Neuropathy Induced By Deficiency of Complex I," <i>Ann. Neurol.</i> , 56 (2):182-91, August 2004.
		QI <i>et al.</i> , "Suppression of Complex I Gene Expression Induces Optic Neuropathy," <i>Ann. Neurol.</i> , 53 (2):198-205, February 2003.
		SHAW <i>et al.</i> , "An Allele-Specific Hammerhead Ribozyme Gene Therapy For a Porcine Model of Autosomal Dominant Retinitis Pigmentosa," <i>Mol. Vis.</i> , 7 :6-13, January 2001.
		SHAW <i>et al.</i> , "Decreased Expression of the Insulin-like Growth Factor 1 Receptor by Ribozyme Cleavage," <i>IOVS</i> , 44 (9): 4105-4113, September 2003.
		SHAW <i>et al.</i> , "Ribozymes in Treatment of Inherited Retinal Disease," <i>Methods Enzymol.</i> , 316 :761-76, 2000.
		International Search Report PCT/US02/13679; April 04, 2005.
		International Preliminary Examination Report PCT/US02/1379; September 15, 2005.

Examiner Signature	Date Considered
--------------------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.